

Import of Cosmetics to Japan

One of the largest markets for cosmetics and personal care products, Japan has a long tradition of using cosmetics, which makes the Japanese consumers particularly conscious of the safety, quality and value of their purchases. In this regard, the cosmetics industry in Japan is governed by the Pharmaceutical and Medical Device Law (PMDL), formerly known as the Pharmaceutical Affairs Law.



Definition of Cosmetics

PMDL defines cosmetics as “articles with mild action on human body by rubbing, sprinkling or other method, aiming to clean, beautify and increase the attractiveness, alter the appearance or to keep the skin or hair in good condition”. In the Japanese market, cosmetics are further classified into six different categories:

| Category | Definition |
|----------------------------|--|
| Perfume and Eau de Cologne | Perfume and Cologne |
| Makeup cosmetics | Foundation creams, lipsticks, eye makeup, etc. |
| Skin care cosmetics | Skin lotion, essence, skin milk, cleansing cream, etc. |
| Hair care cosmetics | Hair dye, shampoo, hair treatment, etc. |
| Special-purpose cosmetics | Sunscreen, shaving cream, etc. |
| Cosmetics soaps | Soaps for cosmetics |

Statutory Representative in Japan

The PMDL does not permit a foreign company to make direct application for a license to market cosmetics products to Japan from overseas. Therefore, any foreign company that wishes to export its products to Japan must first assign a qualified Japanese importer or agent, or it has to set up its own subsidiary in the country. Manufacturers without an office in Japan must have a Marketing Authorization Holder (MAH) to fulfill the requirement.

Cosmetics Ingredient Analysis

The Cosmetics Standards define ingredients that are subject to prohibition or restriction in product combinations. Antiseptics, ultraviolet ray absorbents and tar coloring are subject to positive list (maximum quantity permitted); others are covered by negative list that either prohibits or limits them. In any event, the entire list of ingredients shall be shown in the labeling. Ingredient assessment must be carried out by testing and inspection facilities approved by the Ministry of Health, Labor and Welfare (MHLW).

Application for Licenses

License for Marketing Cosmetics on a Commercial Basis

A company that intends to market or import cosmetics products must obtain a license for marketing cosmetics on a commercial basis from respective local prefecture offices. To obtain such license, the applicant company is required to comply with GQP (Good Quality Practice) and GVP (Good Vigilance Practice) in terms of quality control and post-marketing safety management in accordance with the standards specified by MHLW Ministerial Ordinances.

License for Manufacturing Cosmetics

A company that intends to manufacture cosmetics products must obtain a license for manufacturing cosmetics from respective local prefecture offices. A manufacturer of cosmetics must designate a responsible engineering manager who supervises practical manufacturing of cosmetics for each manufacturing establishment. Even if no packing process is necessary, importer must obtain such license under a classification of “packaging, labeling and storage only” as cosmetics products must be temporarily stored in a facility during testing or clearance processes.

Labeling

PMDL also stipulates that containers or wrappers of cosmetics products shall show the name and address of the marketer, name of product, production number or production code, name of cosmetic ingredients contained, shelf life of cosmetics if the product concerned is not stable for three years, and other information required by the MHLW ordinance.

Notifications and Importation

Once the cosmetics products have been tested and upon receipt of marketing/manufacturing licenses, the importer has to file three notifications to respective government agencies before importation:

| Notification | Responsible administrative agency |
|--|---|
| Manufacture and Sales of Cosmetics Notification | Same prefecture as where licenses are granted |
| Cosmetics Import Notification for Manufacturer and Sales | Regional Bureau of Health and Welfare |
| Manufacturer's or Importer's Brand Name | Pharmaceuticals and Medical Devices Agency |

About STC

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|---------------|------------------------|------------------------|--|
| United States | Tel: +1 201 391 4727 | Fax: +1 201 391 7066 | E-mail: usstc@stc.group |
| Hong Kong | Tel: +852 2666 1888 | Fax: +852 2663 1284 | E-mail: hkcfid@stc.group |
| Dongguan | Tel: +86 769 8111 9888 | Fax: +86 769 8111 9090 | E-mail: dgcfd@stc.group |
| Shanghai | Tel: +86 21 5219 8248 | Fax: +86 21 5219 8249 | E-mail: shcfid@stc.group |

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